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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/561,199 | 12/19/2005 | Peter Nordberg | 1103326-0901 | 3893 |
| 7470 | 7590 | 05/21/2009 | | |
| WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036 | | | EXAMINER SPIVACK, PHYLLIS G | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/561,199

Applicant(s)

NORDBERG, PETER

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's Response filed February 23, 2009 is acknowledged. Claims 1-3, 5, 7 and 8 remain under consideration.

An amendment to the title of the invention is noted. However, there is a spelling error. The compound "imidazo pyradine" should be -- imidazopyridine --. A suggested title is -- Imidazopyridine Compounds, Processes for Their Preparation and Therapeutic Uses thereof --.

A new Abstract is noted. However, the abstract of the disclosure remains objected to because there are no methods of prevention. Correction is required. See MPEP § 608.01(b).

A Terminal Disclaimer filed February 23, 2009 is acknowledged and accepted.

A complete listing of co-pending and related applications of the instant inventor Peter Norberg is requested when Applicant responds to this Office Action.

On page 7 of the Reply filed February 23, 2009, reference is made to "the comparative data set forth in the Declaration submitted herewith." No such declaration is noted.

Those objections and rejections set forth in the last Office Action that are not herein reiterated are withdrawn. The objections and rejections set forth herein constitute the only objections and rejections presently applied to the instant claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5, 7 and 8 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 and 15-22 of copending Application No. 6,313,137. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same compounds of instant Formulas I and III are encompassed, for example, in claim 1 in column 33, and claim 22, column 42, respectively, when the groups R^1 , R^2 , R^3 and R^4 are, or may be, methyl, R^5 and R^7 are hydrogen, R^6 may be hydroxylated C_1 - C_6 alkyl and X may be nitrogen. The required mesylate salt of instant claim 2 is recited in claim 5, column 34. Methods of preparation of the compound of instant Formula I are described in reference claim 10, columns 38-39, wherein a compound of reference Formula XVII (R^{10} is an alkyl group) is treated with an acid or base under standard conditions to produce a compound of instant Formula III. A compound of instant Formula III is reacted with a compound of reference Formula III, wherein R^6 is hydroxylated C_1 - C_6 alkyl and R^7 is hydrogen, in the presence of a coupling agent. See claims 12 and 13, column 39, wherein methods of inhibiting gastric acid secretion are further disclosed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Amin et al., U.S. Patent 6,313,137.

The compound of instant claim 8 is disclosed in claim 22, column 42, when the groups R^1 , R^2 , R^3 and R^4 are, or may be, methyl, R^5 is hydrogen and X may be nitrogen.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Amin et al., U.S. Patent 6,313,136.

The compound of instant claim 8 is disclosed in claim 19, column 38, when the groups R^1 , R^2 , R^3 and R^4 are, or may be, methyl, R^5 is hydrogen and X may be nitrogen.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amin et al., U.S. Patent 6,313,137.

Amin teaches the compound of instant formula I in reference claim 1, column 33, wherein the groups R^1 , R^2 , R^3 and R^4 are, or may be, methyl, R^5 and R^7 are hydrogen, R^6 may be hydroxylated C_1 - C_6 alkyl and X may be nitrogen. Further, a homologue of

instant Formula I appears in column 33, lines 57-58, and column 34, lines 36-37, i.e., 2,3-dimethyl-8-(2,6-dimethylbenzylamino)-N-hydroxyethyl-imidazo[1,2-a]pyridine-6-carboxamide. The compound of instant formula I has an isopropyl group in place of the recited ethyl group. As required by instant claim 2, a mesylate salt of the compound of reference formula I is recited in claim 5, column 34. As required by instant claim 7, see claims 12 and 13, column 39, wherein methods of inhibiting gastric acid secretion and treating gastrointestinal inflammatory diseases are disclosed. As required by instant claim 5, pharmaceutical formulations comprising a compound of reference formula I in combination with a pharmaceutically acceptable diluent or carrier are taught in claim 11, column 39.

The compound of instant claim 8 is disclosed in claim 22, column 42, when the groups R^1 , R^2 , R^3 and R^4 are, or may be, methyl, R^5 is hydrogen and X may be nitrogen.

With respect to processes for the preparation of the compound of instant Formula I, Amin teaches methods of preparation of said compound of instant Formula I in reference claim 10, columns 38-39, wherein a compound of reference Formula XVII (R^{10} is an alkyl group) is treated with an acid or base under standard conditions to produce a compound of instant Formula III. A compound of instant Formula III is reacted with a compound of reference Formula III, wherein R^6 may be hydroxylated C_1 - C_6 alkyl and R^7 may be hydrogen, in the presence of a coupling agent in an inert solvent. The specific coupling agent, o-benzotriazol-1-yl-N,N',N'-tetramethyluronium tetrafluoroborate (TBTU), is disclosed in various synthesis examples, such as Examples 1.14-1.16, *inter alia*, columns 20-21.

Thus in view of the teachings of Amin, one skilled in the art would have been motivated to prepare a homologue of 2,3-dimethyl-8-(2,6-dimethylbenzylamino)-N-hydroxyethyl-imidazo[1,2-a]pyridine-6-carboxamide, wherein a three carbon group replaces a two carbon group, particularly because the R⁶ (or R⁷) group of formula I is taught to include any alkyl group having 1-6 carbon atoms. It would have been reasonable to expect such compounds would have been effective in the treatment of gastric acid related diseases and gastrointestinal inflammatory diseases due to the very close structural similarity of the compound of instant claim 1 and the referenced compounds.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 18, 2009

/Phyllis G. Spivack/

Primary Examiner, Art Unit 1614